510(K) SUMMARY

[as required by section 807.92(c)]

Bonastent™ Esophageal

FEB 22 2010

510(k) Number K092144

Applicant's Name:
EndoChoice Inc.
11800 Wills Rd.
Suite 100Alpharetta, GA 30009
Telephone: 770-682-8700
Fax: 770-962-6981

Contact Person:
Name: Shoshana (Shosh) Friedman
Telephone: 704-899-0092
Fax: 704-899-0098
Email: shosh@pushmed.com

Trade Name:

1. Bonastent™ Esophageal

Classification Name: Esophageal prosthesis
Regulation Number: 878.3610
Product Code: ESW
Classification: Class II
Review Panel: Gastroenterology/Urology

Predicate Devices:

- Ultraflex™ Esophageal Stent System by Boston Scientific Corporation, K012883.
- Wallflex Partially Covered Esophageal Stent System by Boston Scientific Corporation, K073266, K091510.
- Choostent™ covered Esophageal Stent by M.I. Tech Co., Ltd., K072094.
- Niti-S Esophageal Stent by Taewoong Medical Co., Ltd., K 080782, K041648)

Device Description:

The Bonastent™ Esophageal Stent is a covered, self-expanding tubular prosthesis designed to maintain patency of esophageal strictures caused by malignant tumors. The Bonastent™ Esophageal stent is pre-loaded on a delivery device. The delivery device is placed over a guide-wire and through the working channel of an endoscope to deliver the stent. The

delivery device is available in two sizes: 5mm and 6mm diameter. The stents are made of Nitinol wire, and are designed to prevent stent migration due to peristaltic motion and tumor in-growth. The stents are available in a variety of diameters and lengths.

Intended Use:

The Bonastent™ Esophageal Stent System is indicated for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistula.

Comparison Characteristics:

The Bonastent™ Esophageal is substantially equivalent to the legally marketed predicate devices mentioned above. The stent is weaved using a hook & cross wire construction which reduces the delivery device diameter. The stent includes 3 groups of 4 radiopaque markers located at the center of the stent as well as at both ends of the stent and two retrieval lassos at both ends of the stent to allow for stent removal/repositioning.

Performance Data:

Performance testing was carried out per FDA document "Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses" to determine the equivalence of the Bonastent™ Esophageal Stent Systems to the predicate devices and to verify the safety and effectiveness.

Conclusion:

Endochoice Inc. believes that, based on the information provided in this submission the Bonastent™ Esophageal is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

EndoChoice, Inc.
c/o Shoshana Friedman, RAC
President & CEO
Push-Med, LLC
1914 J.N. Pease Place
CHARLOTTE NC 28262

FEB 22 2010

Re: K092144
Trade/Device Name: BONASTENT™ Esophageal
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: February 1, 2010
Received: February 1, 2010

Dear Ms. Friedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K092144/S1
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INDICATIONS FOR USE

510(k) Number (if known): K092144

Device Name: BONASTENT™ Esophageal

Indications for Use:

The BONASTENT™ Esophageal Stent System is indicated for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistula.

Prescription Use ___X___. AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K092144

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